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BIOMIRA
DIAGNOSTICS INC.

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510(k) SUMMARY
VISUWELL® REAGIN II

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safety Medical Devices Act of 1990.

Submitter:

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Date Submitted:

June 16, 1995

Device Name:

Trade Name:
Visuwell® Reagin II

Common Name:
Syphilis non-treponemal antibody detection kit

Classification Name:
Treponemal pallidum non-treponemal test reagent, Class II

Device Description:

Visuwell® Reagin II is an enzyme-linked immunosorbent assay for the *in vitro* qualitative detection of non-treponemal (reagin) antibodies in syphilis serology. In this device, serum is incubated with a mixture of cardiolipin, lecithin, cholesterol dried to a polystyrene solid phase.

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Antilipid antibodies react with the lipoidal antigen to form an immune complex. The presence of non-treponemal complexed antibodies is detected with a monoclonal anti-human IgG-peroxidase conjugate. The presence of bound conjugate is detected by the addition of enzyme substrate and subsequent development of colour. The reaction is stopped by the addition of acid and colour intensity is determined spectrophotometrically at 450 nm.

Test results are interpreted relative to a floating cutoff based on the negative control. Positive and negative controls are used for establishing test validity.

Intended Use

Visuwell® Reagin II is an enzyme-linked immunosorbent assay for the *in vitro* qualitative detection of non-treponemal (reagin) antibodies as a screening test in syphilis serology. It is not intended for use in screening blood or plasma donors.

Substantial Equivalence Claim

Visuwell® Reagin II was demonstrated to be substantially equivalent in performance to the following legally marketed reference non-treponemal tests:

Venereal Disease Research Laboratory (VDRL) Slide Test
Rapid Plasma Reagin (RPR) Card Test
Reagin Screen Test (RST)

Visuwell® Reagin II has the same intended use for screening in syphilis serology but different technological characteristics than the above mentioned reference tests. These tests employ lipoidal antigen comprised of cardiolipin, lecithin and cholesterol.

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Results in the reference tests are interpreted subjectively according to the presence or absence of flocculation as opposed to the objective spectrophotometric interpretation of results using Visuwell® Reagin II.

To demonstrate substantial equivalence, Visuwell® Reagin was compared to the reference tests in specificity, sensitivity, predictive values, cross-reactivity and overall agreement of test results.

Specificity Comparison

Specificity results were obtained from 10,738 specimens in random, low-risk and high-risk populations. The specificity of Visuwell® Reagin II was 97.1% compared to the 99.5% specificity of the reference non-treponemal tests. Visuwell® Reagin II is substantially equivalent to non-treponemal reference tests in specificity.

Sensitivity Comparison

Sensitivity results were obtained from the specimens of 306 patients with untreated syphilis, 74 patients whose treatment status was unknown and 325 patients with treated syphilis.

Visuwell® Reagin II was reactive with 92.2% of specimens from patients with untreated syphilis as compared to 95.8% of specimens with the reference tests. Where treatment status of the patients was unknown, Visuwell® Reagin II was reactive with 93.2% of the specimens as compared to 82.4% of the specimens with the reference tests. Visuwell® Reagin II was reactive with 75.4% of specimens from patients with treated syphilis as compared to 90.2% of the specimens with the reference tests.

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Therefore, Visuwell® Reagin II is substantially equivalent to reference non-treponemal tests in the detection of non-treponemal antibody in sera of patients with untreated syphilis. Visuwell® Reagin II shows lower reactivity with sera from patients with treated syphilis which may suggest potential for monitoring response to therapy.

Predictive Values

The predictive values of positive for syphilis in Visuwell® Reagin II and the reference tests were determined for the Sexually Transmitted Disease (STD) population. The predictive values of negative were determined with data from all sites. The predictive value of positive for Visuwell® Reagin II was 97.4% as compared to 99.4% for the reference tests. The predictive value of negative for Visuwell® Reagin II was 99.0% as compared to 99.5% for the reference tests.

Consequently, Visuwell® Reagin II is substantially equivalent to reference tests in predictive value of positive for STD populations and predictive value of negative.

Cross-Reactivity

Cross-Reactivity results were obtained from 151 specimens consisting of specimens from individuals with a variety of bacterial, viral and auto-immune disorders. Specimens identified as syphilis biological false-positives and specimens from conditions frequently associated with false reactivity in non-treponemal screen tests such as pregnancy and drug abuse were included in these results.

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The specificity of Visuwell® Reagin II in the clinical population characterized by non-syphilitic diseases or conditions was 86.8% as compared to 91.9% with the reference tests. These results indicate that the performance of Visuwell® Reagin II is substantially equivalent to the reference tests for specimens that have potential for interference.

Overall Agreement

The overall agreement between the Visuwell® Reagin II and the reference tests results for all sera (11,443 specimens) was 96.5%. Visuwell® Reagin II is substantially equivalent to non-treponemal reference tests in overall agreement of test results.

Conclusion

The safety and effectiveness of Visuwell® Reagin II is substantially equivalent to legally marketed non-treponemal reference tests (VDRL, RPR, RST) as demonstrated in the comparison of the performance of Visuwell® Reagin to these tests.

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